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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,267	01/27/2004	Darryl J.C. Pappin	BP0207-US 3	9577
23544	7590	03/20/2006	EXAMINER	
APPLIED BIOSYSTEMS 500 OLD CONNECTICUT PATH FRAMINGHAM, MA 01701			GRAZIER, NYEEMAH	
		ART UNIT	PAPER NUMBER	
		1626		

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/765,267	PAPPIN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Nyeemah Grazier	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 December 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-5,8-16,18-29,31-42,44-53,71 and 72 is/are pending in the application.
  - 4a) Of the above claim(s) 72 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3,4,8,10,11,15,20,33,41, 42, 44-53 and 71 is/are rejected.
- 7) Claim(s) 2,5,9,12-14,16,18,19 and 21-27 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/20/05, 12/09/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### **I. ACTION SUMMARY**

Claims 2-5, 8-16, 18-29, 31-42, 44-53, 71 and 72 are currently pending. Claim 1, 6-7, 17, 30, 43, and 54-70 are cancelled. Claim 71 is newly added and hereby withdrawn as not being drawn to the elected invention, namely compounds. Claim 72 is withdrawn as being drawn to an non-elected invention. 37 C.F.R. § 1.142(b).

### **II. INFORMATION DISCLOSURE STATEMENT**

The supplemental information disclosure statements (IDS) submitted on January 20, 2006 and December 19, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. The supplemental IDS submitted on January 20, 2006 is not in compliance with 37 CFR 1.98 because dates for references with citation number HF and HG do not have dates. Please provide date for these references.

### **III. RESTRICTION/ELECTION**

#### ***A. Response to Formal Matters***

Applicant's election with traverse of Group (I), originally claims 1-53, drawn to compounds and compositions, in the reply filed on December 19, 2005 is acknowledged. Applicant has submitted Amendments to the Claims on December 19, 2005. The elected

Art Unit: 1626

invention reads on claims 2-5, 8-16, 18-29, 31-42, 44-53, and 71. The traversal is on the ground(s) that the restriction within Group (I), is improper under 35 M.P.E.P. §803.02. (See Remarks, pp. 27-29). This is not found persuasive because as stated in the Actions, the inventions of Group (I), namely, claim 1 (now cancelled) are independent and distinct.

The election of specie requirement was a *provisional election for search purposes*. Alternatively the compounds and compositions of group (I) present a burden because the compounds are independent and distinct. For example, a 7 membered heterocyclic rings containing at least one nitrogen are classified in the U.S. Classification System in class 540, while a 6 membered heterocyclic rings containing at least one nitrogen and one or more heteroatoms are classified in class 544 and other six membered heterocyclic rings containing one nitrogen are classified in 546. Five membered rings containing at least one nitrogen are classified in class 548. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

**B. Response to Arguments**

***1. Obviousness-Type Rejection***

Applicant's arguments, see Remarks, filed on December 19, 2005, with respect to the provisional double patenting rejection have been fully considered. In view of the amendments to

Art Unit: 1626

the claims filed on December 19, 2005, claims 2-14 depend from new claim 71, which is drawn to a morpholine and not a piperazine. Thus the rejection of claims 2-14 have been obviated.

However, applicants arguments pertaining to the obviousness rejection of claims 41-53 is not persuasive and is therefore maintained. To obviate this rejection, the applicant should submit a terminal disclaimer.

### ***2. 35 U.S.C. 112,1<sup>st</sup> Rejection***

Applicant's arguments, see Remarks, filed on December 19, 2005, with respect to 35 U.S.C. 112 rejection with respect to claims 41 and 49 have been fully considered and are persuasive. The rejection is withdrawn.

### ***3. 35 U.S.C. 112,2<sup>nd</sup> Rejection***

Applicant's arguments, see Remarks, filed on December 19, 2005, with respect to 35 U.S.C. 112, 2nd rejection with respect to claims 41-53 and 1, 15, 23, 28, 36, 41 and 49 have been fully considered. Upon further consideration of the claim amendments, the rejections have been obviated.

## **IV. REJECTION(S)**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1626

Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Claims 71 states “each carbon of the heterocyclic ring has the formula CJ<sub>2</sub>.” However, the definition of J<sub>2</sub> is neither disclosed in the Specification nor the claim. The variable J<sub>2</sub> is unclear because J<sub>2</sub> may be an independent variable or maybe Applicant means to say C(J)<sub>2</sub>.

Claims 3 and 4 recites the limitation "one or more substituent" in reference to substitution on the piperidine ring of claim 71. There is insufficient antecedent basis for this limitation in the claim because the structure appears to be drawn to a piperidine ring with one substitution, namely "W." Claim 71 states that each carbon member of the ring has the formula CJ<sub>2</sub>, but "J<sub>2</sub>" is ambiguous as it has not been defined and it is undetermined whether applicant intend C(J)<sub>2</sub>.

Claim 10 recites the limitation “ wherein the compound is a salt.” There is insufficient antecedent basis for the abovementioned limitation because claim 71 is not drawn to a salt form.

Claim 8 recites the limitation “ wherein the six member heterocyclic ring comprises one or more additional nitrogen, oxygen or sulfur atom.” There is insufficient antecedent basis for the abovementioned limitation because claim 8 depends from claim 71 and claim 71 is drawn to a piperidine ring.

Art Unit: 1626

Claim 11 recites the limitation “ wherein the compound is a mono-TFA salt, a mono-HCl salt, a bis-TFA salt or a bis-HCl salt” There is insufficient antecedent basis for the abovementioned limitation because claim 71 is not drawn to a salt form.

Claims 20, 33 and 46 recite the limitation “methoxy.” There is insufficient antecedent basis for the abovementioned limitation because the claims from which the rejected claims depend (*i.e.* 15, 28 and 41, respectively) do not recite methoxy as a definition for z’.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by *Banasiak, et al.*, (EP 209763 A1). The *Banasiak, et al.* reference discloses 2, 6-dimethyl, 4-nitrophenyl morpholinacetic acid. (See, Attachment A, Accession No. 1987:156487 HCPLUS). The reference anticipates the instant invention wherein x’ is oxygen, LG is 4-nitrophenyl, and where z’ (ortho to the oxygen atom on the morpholine ring) are CH3 and the other is hydrogen.

Claims 41, 44 and 46 are rejected as being anticipated by *Sawayama, et al.*, (JP 01125357 A2). (See, Attachment B, Accession No. 1990:7937 HCPLUS). The *Sawayama, et al.*

Art Unit: 1626

reference anticipates the instant invention where x' is oxygen, z' is methyl at the N-linked carbon), LG is 2,5-pyrrolidinedione and where Pg is a benzyl group.

#### V. ALLOWABLE SUBJECT MATTER

The allowable subject matter includes the compounds and compositions of claims 28, 29, 31-32, 34-40.

#### VI. OBJECTION(S)

##### Dependent Claim Objections

Dependent Claims 2-14, 16, 18-27, 42, and 44-53 are also objected to as being dependent upon a rejected based claim. To overcome this objection and assuming the dependent claim is not rejected, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

#### VII. CONCLUSION

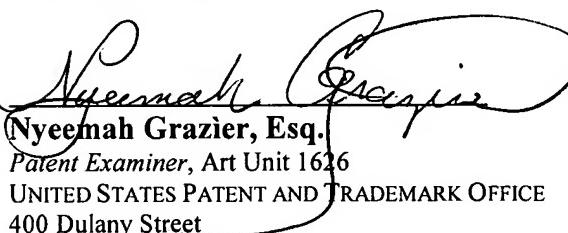
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1626

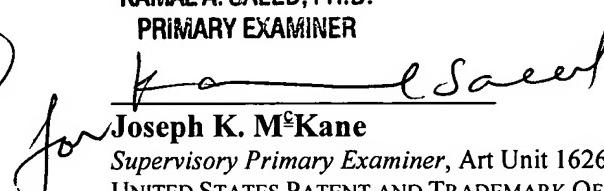
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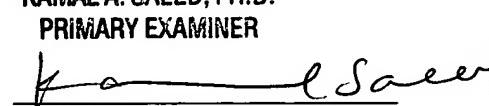
Very truly yours,

  
**Nyeemah Grazier, Esq.**

Patent Examiner, Art Unit 1626

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**ATTACHMENT A**

Application/Control Number: 10/765,267  
Art Unit: 1626

Page 10

**ATTACHMENT B**